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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,485	11/14/2001	Michael A. Barry	15987/282434	7070
22242	7590	03/24/2004	EXAMINER	
FITCH EVEN TABIN AND FLANNERY 120 SOUTH LA SALLE STREET SUITE 1600 CHICAGO, IL 60603-3406			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/987,485	<b>Applicant(s)</b> BARRY ET AL.	
	<b>Examiner</b> Bao Qun Li	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-49 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/30/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment, paper No. 15, filed 12/30/03. Claims 1-36 have been canceled. New claims 37-49 are added. Claim 10 is amended. Claims 37-49 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 12/30/2003 was filed after the mailing date of the first Office Action on 07/02/2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS has been considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 37 and 39 are still rejected under 35 U.S.C. 102(b) as being anticipated by Cronan et al. (US Patent No. 5,252,466A).
3. In response to the previous Office Action, Applicants cancel the claims 1-36 and file a new set of claims. Applicants then, submitted that the new claims have incorporated the limitation of original claim 17, asserting that the new claims will not be anticipated by the cited prior art.
4. Applicants' amendment as well as the argument have been respectfully considered; however, it is not found persuasive because the recitation of "consisting essentially of" still leave the claim open. The examiner should broadly interpret the claim as reading on more than the SEQ ID NO: 2. Accordingly the examiner should apply art in the event that such art is available.

Art Unit: 1648

The examiner should state on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein. According to the MPEP " [it] is an applicant's burden to establish that a step in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03.

5. In the instant case, the claimed fusion protein still read on the fusion polypeptide disclosed by Cronan et al. still read on a fusion polypeptide. Because the fusion protein disclosed by Cronan meet all limitation of fusion protein comprising the 1.3 S subunit of *P. Schermanii* transcarboxylase (PSTCD) fused to the  $\beta$ -galactosidase, in which the PSTCD peptide contains a fragment having 100% identical amino acid sequence to the claimed PSTCD peptide of SEQ ID NO: 2, wherein the said PSTCD peptide is able to undergo biotinylation when it is expressed in the host cell *E. coli*.

6. Moreover, the fusion protein preferably, also comprises a signal or signal-leader sequence, which provides for secretion of the protein or polypeptide from the cell in which it is produced (See lines 18-49 on col. 11 and Fig. 20). Therefore, the claimed invention is still anticipated by the cited reference.

7. Claims 37-38 are still rejected under 35 U.S.C. 102(b) as being anticipated by Cress et al. (EP 0 511 747A1).

8. In response to the previous Office Action, Applicants cancel the claims 1-36 and file a new set of claims. Applicants then, submitted that the new claims have incorporated the limitation of original claim 17, asserting that the new claims will not be anticipated by the cited prior art.

9. Applicants' amendment and argument have been respectfully considered; however, it is not found persuasive because the amendment of "consisting essential of" in the claim 37 still leave the claim open, which still read on a fusion polypeptide disclosed by Cress that comprises an interested polypeptide fuse to both ends of 1.3 S subunit of *P. Schermanii* transcarboxylase (PSTCD) (See Fig. 3B-C). The PSTCD contains a fragment having 100% identical amino acid

Art Unit: 1648

sequence to the claimed PSTCD peptide of SEQ ID NO: 2, which enable the fusion polypeptide undergo biotinylation when it is expressed in the host cell.

10. Applicants are reminded that the recitation of "consisting essentially of" still leave the claim open. The examiner should broadly interpret the claim as reading on more than the SEQ ID NO: 2. Accordingly the examiner should apply art in the event that such art is available. The examiner should state on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein. According to the MPEP " [it] is an applicant's burden to establish that a step in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03.

**New Ground Rejections:*****Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Cronan (WO 90/14431A).

4. Cronan discloses a biotinated fusion protein comprising the full-length or part of P. schermanil trancarboxylase (PSTCD) peptide and a polypeptide of  $\beta$ -galactosidase, in which the PSTCD sequence is fused to the C-terminal of the interested polypeptide (Fig. 21). The portion of the PSTCD domain contains the fragment having 100% homology to the claimed PSTCD peptide identified by SEQ ID NO: 2. Moreover, Cronan also teach that the above fusion protein also preferably contains a signal or signal-leader sequence (See pages 22-23).

5. Applicants are reminded that the recitation of "consisting essentially of" still leave the claim open. The examiner should broadly interpret the claim as reading on more than the SEQ

Art Unit: 1648

ID NO: 2. Accordingly the examiner should apply art in the event that such art is available. The examiner should state on the record that the other elements of the prior art (if there are other elements present) do not appear to materially change the characteristics of the protein. In this way applicant will come forth with evidence to show that the extraneous elements in the reference do indeed have a material effect on the characteristics of the protein. According to the MPEP " [it] is an applicant's burden to establish that a step in a prior art method is excluded from his claims by "consisting essentially of" language." Please see MPEP 2111.03. The same analysis applies to product claims. Therefore, the claimed invention is anticipated by the cited reference.

***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claim 37 is rejected under 35 U.S.C. 102(e) as being anticipated by Callister et al. (US Patent No. 6,210,676B1).

7. Callister et al. disclose an isolated fusion protein comprising the an outer surface protein (Osp) polypeptide of *Borrelia burgdoferi* (B.b.) and the biotinylation peptide PSTCD that comprising the same sequence as SEQ ID NO: 1 and SEQ ID NO: 2 because the SEQ ID NO: 2

is the fragment of SEQ ID NO: 1 from amino acid residue 58-122. The recombinant Osp fusion protein can be expressed by E Coli as biotinylated polypeptide because it is fused with the sequence of PSTCD peptide at its C-terminus (See SEQ ID NO: 1, Fig. 4 and examples 1-2 on col. 8-14). It inherently comprises at least 63 amino acid from the C-terminus and with a lysine residue at the same position as it is claimed in SEQ ID NO: 2. Therefore, the claimed invention is anticipated by the cited reference.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 37-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cronan (WO 90/14431A), Callister et al. (US Patent 6,210,676B1), Cress et al. (EP 0 511 747A1) and van Raaij et al. (Nature 1999, Vol. 935-938).

10. Claimed invention is drawn to a fusion protein consisting essential of the P. schermanii transcarboxylase domain (PSTCD) peptide of SEQ ID NO: 2 or SEQ ID NO: 1, and a polypeptide of interest, wherein the polypeptide is preferably an adenovirus fiber protein and is fused with the PSTCD at its C-terminus.

11. Cronan discloses a biotinated fusion protein comprising the full-length or part of P. schermanii transcarboxylase (PSTCD) peptide and a polypeptide of  $\beta$ -galactosidase, in which the PSTCD sequence is fused to the C-terminal of the interested polypeptide (Fig. 21). The portion of the PSTCD domain contains the fragment having 100% homology to the claimed PSTCD peptide identified by SEQ ID NO: 2. Moreover, Cronan also teach that the above fusion protein also preferably contains a signal or signal-leader sequence (See pages 22-23). Cronan does not

teach that to the PSTCD peptide if the full-length PSTCD of SEQ ID NO: 1 and the polypeptide of interest is an adenovirus fiber protein.

12. Callister et al. disclose an isolated fusion protein comprising the an outer surface protein (Osp) polypeptide of *Borrelia burgdoferi* (B.b.) and the biotinylation peptide PSTCD that comprising the same sequence as SEQ ID NO: 1 and SEQ ID NO: 2 because the SEQ ID NO: 2 is the fragment of SEQ ID NO: 1 from amino acid residue 58-122. The recombinant Osp fusion protein can be expressed by E Coli as biotinylated polypeptide because it is fused with the sequence of PSTCD peptide at its C-terminus (See SEQ ID NO: 1, Fig. 4 and examples 1-2 on col. 8-14). It is inherently comprises at least 63 amino acid from the C-terminus and with a lysine residue at the same position as it is claimed in SEQ ID NO: 2.

11. Cress et al. disclose a fusion protein comprising an interested polypeptide fused with the 1.3 S subunit of *P. Schermanii* transcarboxylase (PSTCD) (See Fig. 3B-C) and it is attached to the either C-terminus or N-terminus of the PSTCD peptide.

12. Regarding to the limitation of the adenovirus fiber protein used as an interested fusion polypeptide, the sequence structures of an adenovirus fiber proteins are well known in the art, such as van Raaij et al. disclose a full-length sequence of adenovirus 2 fiber protein (Fig. 2 on page 936).

13. Therefore, Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references of Cronan, Cress and Callister et al. to make a fusion protein made by an adenovirus fiber protein in view of the disclosure in the prior art, such as by Raaij et al. since the method of using the PSTCD peptide to make the biotinylated antigen polypeptide is well described in the prior art as disclosed by cited references. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

### ***Conclusion***

No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



Art Unit: 1648

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

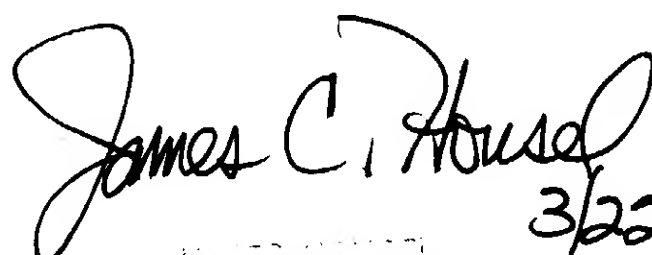
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0906. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

March 17, 2004

  
3/22/04  
JAMES C. HOUSEL  
SUPERVISOR